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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MACIAS, CHANDA L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,440	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Chanda L. Macias	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-39 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, insofar as the claims drawn to an expression vector, or a composition thereof, comprising the nucleic acid sequence in SEQ ID NO: 1 or a fragment thereof, classified, for example, in class 435, subclass 320.1.

II. Claims 1-30, insofar as the claims drawn to an expression vector, or a composition thereof, comprising the nucleic acid sequence in SEQ ID NO: 3 or a fragment thereof, classified, for example, in class 435, subclass 320.1.

III. Claims 31-35, insofar as the claims are drawn to a method for preventing or treating cancer comprising administering to a host an expression vector comprising the nucleic acid sequence of SEQ ID NO: 1 or a fragment thereof, classified, for example, in class 514, subclass 44.

IV. Claims 31-35, insofar as the claims are drawn to a method for preventing or treating cancer comprising administering to a host an expression vector comprising the nucleic acid sequence of SEQ ID NO: 3 or a fragment thereof, classified, for example, in class 514, subclass 44.

V. Claim 36, drawn to a peptide derived from BFA4, classified, for example, in class 530, subclass 300.

VI. Claim 37, drawn to a method of immunizing a host against the tumor antigen BF4A comprising administering to the patient a peptide derived from BF4A, classified, for example, class 424, subclass 185.1.

VII. Claim 38, drawn to a peptide derived from BCY1 thereof classified, for example, class 530, subclass 300.

VIII. Claim 39, drawn to a method for immunizing a host against the tumor antigen BCY1 comprising administering to the patient a peptide derived from BCY1, classified, for example, class 424, subclass 277.1

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, V, and VII are products, whereas the inventions of Groups III, IV, VI, and VIII are processes.

The inventions of Group I and the inventions of Groups IV, VI, and VIII are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups IV, VI, VIII.

The inventions of Group II and the inventions of Groups III, VI, and VIII are unrelated because the products of Group II are not specifically used or otherwise involved in the processes of Groups III, VI, and VIII.

The inventions of Group V and the inventions of Groups III, IV, and VIII are unrelated because the products of Group V are not specifically used or otherwise involved in the processes of Group III, IV, and VIII.

The inventions of Group VII and the inventions of Groups III, IV, and VI are unrelated because the products of Group VII are not specifically used or otherwise involved in the processes of Groups III, IV, and VI.

The inventions of Groups I and II and the inventions of Groups III and IV, respectively, are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely an expression

vector can be used in a materially different process of using that product, such as the process of making a polypeptide encoded by the vector.

The inventions of Groups I - II and III - IV have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group I - II would not suffice to provide adequate information regarding the merit of the claims of Group III - IV, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and III, an examination of both would constitute a serious burden.

Since the inventions of Groups I - II and III - IV have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups I - II and V, VII are patentably distinct products for the following reasons:

The inventions of Groups I and II are patentably distinct inventions because the inventions of Group I are expression vectors comprising the nucleic acid sequence of SEQ ID NO: 1 or a fragment thereof, whereas he inventions of Group I are expression vectors comprising the nucleic acid sequence of SEQ ID NO: 3 or a fragment thereof. SEQ ID NO: 1 and SEQ ID NO: 3 are different polynucleotide sequences encoding different proteins. As such, the search required to examine claims directed to either one of these inventions is different from that required to examine claims directed to the other. Having to perform more than one search would constitute a serious burden.

The inventions of Groups V and VII are patentably distinct inventions because the inventions of Group V are peptides derived from "BFA4", whereas he inventions of Group V are peptides derived from "BCY1". BFA4 and BCY1 are described as different proteins comprising relatively unique amino acid sequences. As such, the search required to examine claims directed to either one of these inventions is different from that required to examine claims directed to the other. Having to perform more than one search would constitute a serious burden.

The inventions of Groups I-II are expression vectors (e.g., plasmids or viral vectors), which are comprised at least in part of nucleic acid molecules, whereas the inventions of Groups V and VII are peptides. Peptides and nucleic acid molecules are chemically distinct products, since peptides are composed of monomers of amino acids, whereas nucleic acids are composed of monomers of nucleotides. Any relationship between a nucleic acid and a peptide is dependent upon the information provided by the nucleotide sequence of the nucleic acid, as it corresponds to an "open reading frame" encoding the amino acid sequence of the peptide. However, a peptide can be produced by means, other than the recombinant means by which a nucleic acid encoding a peptide might be used to produce the peptide, since a peptide can be synthesized or produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the nucleic acid might encode the peptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a nucleic acid can be used as a probe in hybridization-based analyses, the information provided by a nucleic acid can be used isolate different nucleic acids encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed nucleic acid. Consequently, the disclosed relationship between a nucleic acid capable of encoding a peptide and the peptide is not exclusive, since either the claimed nucleic acid or the claimed peptide can also be related to other nucleic acids or peptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups I - II and V, VII are patentably distinct products.

The inventions of Groups I - II and V, VII have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a nucleic acid is a different from the search performed in examining claims drawn to a peptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Groups I- II would not suffice to provide adequate information regarding the merit of the claims of Group V, VII, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I-II and V, VII, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the nucleic acid and the peptide encoded by the nucleic acid is not absolute or exclusive of other relationships with different nucleic acids or peptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Groups I, II, V, and VII are patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups III, IV, VI, and VIII are unrelated, or are otherwise patentably distinct, each from the other, for the following reasons:

The inventions of Groups III and IV are methods for preventing or treating cancer comprising administering to a host an expression vector (e.g., a plasmid or viral vector), whereas the inventions of Groups VI and VIII are methods of immunizing a host against a tumor antigen comprising administering to a host a peptide.

Although both the inventions of Groups III and IV are methods for preventing or treating cancer comprising administering to a host an expression vector, the expression

vectors comprise different polynucleotide sequences encoding different proteins. Therefore, the inventions of Groups III and IV are necessarily effective for preventing or treating cancer associated with the expression and/or activity of different proteins; and the types of cancer that are prevented or treated are necessarily the same.

Although the inventions of Groups VI and VIII are methods of immunizing a host against a tumor antigen comprising administering to a host a peptide, the peptide that is administered to the host in practicing the different inventions is derived from different proteins. Accordingly, the inventions of Groups VI and VIII necessarily elicit different immune responses in the hosts.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that any of the inventions of Groups III, IV and VI, VIII are useable together. Therefore, because the inventions of Groups III, IV and VI, VIII have different purposes, the inventions appear unrelated.

If not unrelated, the inventions of Groups III, IV and VI, VIII are patentably distinct, each from the others, for the following reasons:

As the claims are written, the inventions of Groups III, IV and VI, VIII have different purposes or objectives. As such, the inventions of Groups III and IV and the inventions of Groups VI and VIII necessarily involve the measurement of different endpoints and have different criteria for success.

In addition, as already explained, the inventions of Groups III, IV and VI, VIII are materially different processes comprising different process steps.

Because the inventions of Groups III, IV and VI, VIII are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups III, IV and VI, VIII have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would

have to be performed to examine claims directed to the inventions of Groups III, IV and VI, VIII an examination of both would constitute a serious burden.

Since the inventions of Groups III, IV and VI, VIII have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims 1-35 directed to patentably distinct species of the claimed inventions of Groups I-IV, wherein said expression vector is selected from the group consisting of (a) plasmid, (b) vaccinia, (c) NYVAC, (d) avipox, (e) canarypox, (f) ALVAC, (g) ALVAC(2), (h) fowlpox, (i) TROVAC, (j) alphavirus, (k) adenovirus, (l) retrovirus, (m) herpesvirus, and (n) adeno-associated virus.

Each different species of these inventions is patentably distinct from the others since each member of the genus of expression vectors is distinct from the others because each is either a plasmid (i.e., a "naked" DNA molecule) or a viral vector (i.e., a recombinant virus), and each different viral vector has a unique structure and is composed of unique proteins and nucleic acid molecules. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one member of the genus of expression vectors will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform

more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the specific type of expression vector to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. This application contains claims 36 and 37 directed to patentably distinct species of the claimed inventions of Groups V and VI, wherein said peptide is selected from the group consisting of BFA4 derived peptides as shown in Table V, VI or VII.

Each species of inventions is patentably distinct from the others since each member of the genus of peptides is distinct from the others because each has a unique amino acid sequence that differs from the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, and the search of any one member of the genus of peptides will not provide adequate information regarding

any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one peptide (selected from Tables V, VI or VII) to which the claim will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. This application contains claims 38 and 39 directed to patentably distinct species of the claimed inventions of Groups VII and VIII, wherein said peptide is selected from the group consisting of BCY1 derived peptides as shown in Table VIII, or IX.

Each species of inventions is patentably distinct from the others since each member of the genus of peptides is distinct from the others because each has a unique amino acid sequence that differs from the others. Accordingly, the examination of

claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, and the search of any one member of the genus of peptides will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one peptide (selected from Tables VIII or IX) to which the claim will be directed during prosecution on the merits, and to which the claim shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chanda L. Macias whose telephone number is (571)272-9032. The examiner can normally be reached on Monday - Friday, 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chanda L. Macias, Ph.D.
Examiner
Art Unit 1643

clm
March 14, 2006

STEPHEN RAWLINGS
PRIMARY EXAMINER
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